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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,979	12/19/2005	Varghese John	02-414-A1	1935

20306 7590 12/16/2008

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EXAMINER	
JAVANMARD, SAHAR	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,979	JOHN ET AL.	
	Examiner	Art Unit	
	SAHAR JAVANMARD	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,23-25 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 23-25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 09/02/2008. Claim(s) 1-7, 23-25 and 27 are pending are examined herein.

Response to Arguments

In view of Applicant's amendments, the 112 1st rejection of claims 1-7 and 23-27 for lack of enablement for the "prevention" of Alzheimer's disease and others is hereby withdrawn.

In view of Applicant's amendments, the 112 1st rejection for scope of enablement of claims 1-7, 24 and 27 is hereby withdrawn.

Applicant's arguments with respect to the 103(a) rejection of claims 1-7 and 23-27 as being unpatentable over Göshke et al (US Patent No. 5,559,111) in view of Savaskan (Neurobiology of Aging, 2001) has been fully considered but found not persuasive.

Applicant argues that the teachings of Savaskan are more conjecture and that the combination of Göshke and Savaskan would not lead one to the reasonable expectation of success.

Examiner respectfully disagrees. Göshke specifically teaches the δ-amino-γ-hydroxy-ω-aryl-alkanoic acid amide compounds for cognitive disorders as stated in the previous office action mailed April 1, 2008. It is well known in the art that Alzheimer's

disease is a cognitive disorder. This alone would be motivation enough to employ the compounds taught by Göshke to treat Alzheimer's disease. Nonetheless, Savaskan was brought in to provide further motivation that since the compounds taught by Göshke possess renin-inhibiting properties and Savaskan teaches that the renin-angiotensin system may be directly responsible for cognitive impairment in AD, then it would be even more obvious for one of ordinary skill in the art to try, with a reasonable degree of success, the compounds of Göshke in the treatment of Alzheimer's disease.

The 103(a) rejection has been maintained for reasons of record and has been incorporated in the office action below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 23-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Göshke et al (US Patent No. 5,559,111) in view of Savaskan (Neurobiology of Aging, 2001).

Göshke teaches δ-amino-γ-hydroxy-ω-aryl-alkanoic acid amides (column 75-76, examples 78 and 79). The compounds are taught as having renin-inhibiting properties and their use as antihypertensive medicinal active ingredients (abstract; column 12, lines 36-39). Specifically, Göshke teaches that the compounds can be used in the treatment of hypertension, congestive heart failure, cardiac hypertrophy, cardiac fibrosis, cardiomyopathy post-infarction, complications resulting from diabetes, such as nephropathy, vasculopathy and neuropathy, diseases of the coronary vessels, restenosis following angioplasty, raised intra-ocular pressure, glaucoma, abnormal vascular growth, hyperaldosteronism, anxiety states and cognitive disorders (column 13, line 65-column 14, line 6).

Göshke further teaches that the compounds can be administered to human beings (column 45, 45-47).

Göshke does not teach the administration of these compounds for the treatment of Alzheimer's disease.

Savaskan teaches the primary function of the renin-angiotensin system (RAS) is to maintain fluid homeostasis and the regulation of blood pressure. Renin, a proteolytic

enzyme secreted by the kidney, acts on angiotensinogen to form the inactive decapeptide angiotensin I, which, in turn, is hydrolyzed by the angiotensin converting enzyme (ACE) to the active octapeptide angiotensin II (page 541, column 1, paragraph 1). Savaskan further teaches that the increased ACE activity may be directly responsible for cognitive impairment in AD since the enhanced formation of angiotensin II would result in increased inhibitory effect of angiotensin II on acetylcholine release. This may explain the behavioral eliciting effects of ACE inhibitors on passive avoidance and retention performance in animal models of memory function page 544, column 2, paragraph 2).

Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the administration δ-amino-γ-hydroxy-ω-aryl-alkanoic acid amides taught by Göshke for the treatment of Alzheimer's disease. As discussed above, Göshke teaches the amide compounds may be used to treat cognitive disorders, of which, as known in the art, Alzheimer's is one. Further motivation, provided by Savaskan, discusses evidence as to how the renin-angiotensin system can be related to Alzheimer's disease and how the administration of inhibitors of this system results in retention of memory function.

Conclusion

Claims 1-7, 23-25 and 27 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617